Amendments to the Claims

This listing of claims will replace all prior versions, and listings, of claims in the application.

Listing of Claims:

1. (Currently Amended) A sustained release oral formulation comprising biodegradable microparticles and/or nanoparticles having dispersed therein a therapeutically effective amount of at least one antioxidant and at least one of isosorbide dinitrate and isosorbide mononitrate, wherein the isosorbide dinitrate is present in an amount of about 30 milligrams per day to about 160 milligrams per day.

2. (Previously Presented) The sustained release oral formulation of claim 1, further comprising a pharmaceutically acceptable carrier.

3. (Previously Presented) The sustained release oral formulation of claim 1, wherein the antioxidant is a small-molecule antioxidant, or a pharmaceutically acceptable salt thereof, or an antioxidant enzyme.

4. (Previously Presented) The sustained release oral formulation of claim 3, wherein the small-molecule antioxidant is a hydralazine compound, a glutathione, a vitamin C, a vitamin E, a cysteine, a N-acetyl-cysteine, a β-carotene, an ubiquinone, an ubiquinol-10, a tocopherol, a coenzyme Q, or a mixture thereof.

5. (Previously Presented) The sustained release oral formulation of claim 3, wherein the antioxidant enzyme is superoxide dismutase, catalase, glutathione peroxidase, or a mixture thereof.

6. (Previously Presented) The sustained release oral formulation of claim 4, wherein the at least one antioxidant is a hydralazine compound or a pharmaceutically acceptable salt thereof.

7. (Previously Presented) The sustained release oral formulation of claim 6, wherein the at least one hydralazine compound is hydralazine hydrochloride.

8. (Previously Presented) The sustained release oral formulation of claim 7, wherein the hydralazine hydrochloride is present in an amount of about 30 milligrams to about 400 milligrams per day.

9. (Previously Presented) The sustained release oral formulation of claim 8, wherein the hydralazine hydrochloride is present in an amount of about 50 milligrams to about 300 milligrams per day.

10-11. (Cancelled)

12. (Previously Presented) The sustained release oral formulation of claim 1, wherein the isosorbide mononitrate is present in an amount of about 5 milligrams per day to about 120 milligrams per day.

13. (Previously Presented) The sustained release oral formulation of claim 12, wherein the isosorbide mononitrate is present in an amount of about 15 milligrams per day to about 100 milligrams per day.

14 - 15 (Cancelled)

16. (Previously Presented) The sustained release oral formulation of claim 1, wherein the sustained release oral formulation is a solid dose, a liquid dose or a suspension.

17. (Previously Presented) The sustained release oral formulation of claim 16, wherein the solid dose is a sustained-release tablet or a sustained release capsule.

18. (Previously Presented) The sustained release oral formulation of claim 1, comprising a therapeutically effective amount of hydralazine hydrochloride and isosorbide dinitrate.

19. (Previously Presented) The sustained release oral formulation of claim 1, comprising a therapeutically effective amount of hydralazine hydrochloride and isosorbide mononitrate.

20. (Previously Presented) The sustained release oral formulation of claim 1, further comprising at least one nitrosated angiotensin-converting enzyme inhibitor, nitrosated beta-adrenergic blocker, nitrosated calcium channel blocker, nitrosated endothelin antagonist and nitrosated angiotensin II receptor antagonist, nitrosated renin inhibitor, or a mixture thereof.

21. (Previously Presented) The sustained release oral formulation of claim 1, further comprising at least one compound used to treat cardiovascular diseases, or a pharmaceutically acceptable salt thereof.

22. (Previously Presented) The sustained release oral formulation of claim 21, wherein the at least one compound used to treat cardiovascular diseases is an angiotensin-converting enzyme inhibitor, a beta-adrenergic blocker, a cholesterol reducer, a calcium channel blocker, an angiotensin II receptor antagonist, an endothelin antagonist, a renin inhibitor, or a mixture thereof.

23. (Original) A method of treating a vascular disease characterized by a nitric oxide insufficiency in a patient comprising administering to the patient the sustained release formulation of claim 1.

24. (Original) The method of claim 23, wherein the vascular disease characterized by nitric oxide insufficiency is a cardiovascular disease; a disease resulting from oxidative stress; low-renin hypertension; salt-sensitive hypertension; low-renin, salt-sensitive hypertension; primary pulmonary hypertension; thromboembolic pulmonary hypertension; pregnancy-induced hypertension; renovascular hypertension; hypertension-dependent end-stage renal disease; heart failure; microvascular cardiac ischemia; left ventricular hypertrophy with disproportionate microvascularization or diastolic dysfunction.

25. (Original) The method of claim 24, wherein the cardiovascular disease is congestive heart failure, hypertension, pulmonary hypertension, myocardial and cerebral infarctions, atherosclerosis, atherogenesis, thrombosis, ischemic heart disease, post-angioplasty restenosis, coronary artery diseases, renal failure, stable, unstable and variant (Prinzmetal) angina, cardiac edema, renal insufficiency, nephrotic edema, hepatic edema, stroke, transient ischemic attacks, cerebrovascular accidents, restenosis, controlling blood pressure in hypertension, platelet adhesion, platelet aggregation, smooth muscle cell proliferation, vascular complications associated with the use of medical devices, wounds associated with the use of medical devices, pulmonary thromboembolism, cerebral thromboembolism, thrombophlebitis, thrombocytopenia or bleeding disorders.

26-169 (Cancelled)